

### **REMARKS**

Reconsideration and withdrawal of the rejections of the application respectfully requested in view of the remarks and enclosures herewith, which place the application in condition for allowance.

#### **I. STATUS OF CLAIMS AND FORMAL MATTERS**

Claims 1-7, 25-27, 34 and 35 are pending in this application.

The Examiner is thanked for indicating that claims 27, 34 and 35 are allowable over the prior art of record.

It is submitted that the claims as originally presented were in full compliance with the requirements of 35 U.S.C. § 112. The amendments of the claims, as previously presented, were not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions were made simply for clarification and to round out the scope of protection to which Applicants are entitled.

#### **II. THE SECTION 112 REJECTIONS ARE OVERCOME**

Claims 1-7 and 25-26 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement. The rejection is respectfully traversed.

According to the Court of Appeals for the Federal Circuit in the case of *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988),

Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. 'The key word is undue, not experimentation.' The determination of what constitutes undue experimentation in a given case requires the application of standard of reasonableness, having due regard for the nature of the invention and the state of the art. The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed ... [Citations omitted]. *Id.* at 1404.

Determining whether undue experimentation is required to practice a claimed invention turns on weighing many factors summarized in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988), for example: (1) the quantity of experimentation necessary; (2) the amount of direction or guidance presented; (3) the presence or absence of working examples of the invention; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of

those in the art; (7) the predictability or unpredictability of the art; and (8) the breadth of the claims.

Thus, it is respectfully submitted that for a proper Section 112, first paragraph, lack of enablement analysis, an Office Action must show that the *Wands* factors are not met. Simply, it is respectfully asserted that the lack of enablement rejection fails to provide a fact based analysis using the *Wands* factors that supports the proposition the claimed invention require undue experimentation.

The Examiner is respectfully reminded that a specification need not contain any example of the invention, as the issue is whether the disclosure enables one skilled in the art to practice the invention without undue experimentation. *In re Borkowski*, 422 F.2d 904, 164 USPQ 642 (CCPA 1970). Simply, a determination that undue experimentation is necessary to practice the invention does not necessarily follow from a lack of examples in the specification. And, the Examiner is further respectfully reminded that an applicant need not describe all actual embodiments of a claimed invention.

The Examiner alleges that the specification, while being enabling for the few examples given, does not reasonably provide enablement for all and any substance that may or may not meet the criteria recited in the claims. The Examiner also alleges that one of ordinary skill in the art would have to experiment unduly to determine which compounds or substances beyond the examples given would work as “a substantially biologically inert proto-drug”, “a substantially inert activation drug”, “a differentially selective moiety”, “a toxic moiety”, “a cap moiety” and “substantially inert activation drug”. Applicants disagree and traverse the rejection.

Accompanying this response is a true copy of a Declaration Under 37 C.F.R. § 1.132 by Eduardo Palomino. According to the Declaration, the present invention is directed to anticancer drug design comprising a cytotoxic substance or anticancer agent known in the art, for which a basic mechanism of action is known. The Declaration also states that one of ordinary skill in the art, exercising reasonable curiosity, would learn from a modest search of the relevant art, cytotoxic substances or anticancer agents, substances with tissue selectivity, caps and activators based upon the teaching of the specification.

Contrary to the Examiner’s contention, the Declaration states that the terms “a substantially biologically inert proto-drug”, “a substantially inert activation drug”, “a differentially selective moiety”, “a toxic moiety”, “a cap moiety” and “substantially inert” are

definite and adequately supported in the instant specification such that one of ordinary skill in the art would know where to search for known compounds in the art and ascertain the metes and bounds of the compounds that fall within the purview of the claims without undue experimentation.

Therefore, there is a failure to provide a factual showing that the present application is not enabled. Absent factual evidence corresponding to the *Wands* factors above, the Section 112 rejection is improper and must be withdrawn.

Consequently, reconsideration and withdrawal of the Section 112 rejections is respectfully requested.

**REQUEST FOR INTERVIEW**

If any issue remains as an impediment to allowance, a further interview with the Examiner and SPE are respectfully requested; and, the Office Action is additionally requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

**CONCLUSION**

In view of the remarks and Declaration Under 37 C.F.R. § 1.132 submitted herewith, the application is believed to be in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date, and, the Examiner is invited to telephonically contact the undersigned to advance prosecution.

Respectfully submitted,  
FROMMER LAWRENCE & HAUG LLP

By: Deborah L. Lu  
William S. Frommer  
Reg. No. 25,506  
Deborah L. Lu  
Reg. No. 50,940  
Telephone: (212) 588-0800  
Facsimile: (212) 588-0500